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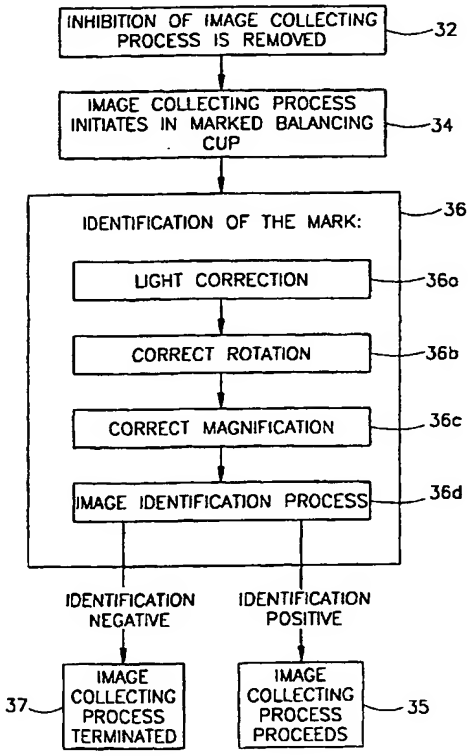
[Continued on next page]

(54) Title: METHOD FOR ACTIVATING AN IMAGE COLLECTING PROCESS



(57) Abstract: The present invention is a method for activating an image collecting process (step 34), comprising the steps of releasing the power source of a component essential to the image collecting process from an inhibition imposed by an external magnet, wherein the invention also provides suitable packaging for storing the imaging system having a magnet, designed for the inside of a body lumen.

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METHOD FOR ACTIVATING AN IMAGE COLLECTING PROCESS

FIELD OF THE INVENTION

The present invention generally relates to a method for the activation of an image collecting process. More specifically, the method of the present invention can be applied to an image collecting process meant for imaging the inside of body lumens.

BACKGROUND OF THE INVENTION

Single chip imaging devices such as charge coupled devices (CCD) and CMOS type image sensors can operate using small power sources and relatively little energy. Such imaging devices are implemented in applications as diverse as star tracking applications and imaging the inside of the gastrointestinal tract.

For example, US 5,604,531, assigned to the common assignee of the present invention, describes a swallowable capsule for imaging the full length of the gastrointestinal tract. The swallowable capsule includes a camera system, an optical system for imaging an area of interest onto the camera system and a transmitter which transmits the video output of the camera system.

In some instances the imaging devices are inaccessible to an operator at the appropriate time for activation, such as for reasons of sterility, and must be activated by remote control such as by IR or radio.

A method for activating a battery, though not a battery of an imaging device, is exemplified in PED Inc's swallowable temperature pill. PED Inc.

advertises a swallowable temperature pill for tracking core body temperature. The temperature pill is powered by a silver oxide battery. The battery is kept turned off during storage by a small magnet that is taped to the pill package and is activated by removing this magnet.

SUMMARY OF THE INVENTION

The present invention relates to a method for activating an image collecting process, comprising the step of releasing the power source of a component essential to the image collecting process from an inhibition imposed by an external magnet. The method enables facile and sterile activation of the image collecting process, since activation of the process does not require directly handling any component participating in the process and does not require a third party, such as a remote control operator.

An image collecting process is a process in which images are obtained and components essential to the image collecting process are those power source driven components whose operation is necessary for obtaining an image. Components essential to the image collecting process may be an imaging device, such as low energy imaging devices, i.e., a CCD camera or a CMOS type image sensor, a light source for illuminating the target to be imaged, etc.

The term power source of a component essential to the image collecting process includes a motor or an engine which utilize a power source for operating the component.

The term "external magnet" in the present invention refers to a magnet positioned relatively to the component or components essential to the image collecting process, such that it is capable of inhibiting the essential component or components power source.

In an embodiment of the invention the image collecting process is designed to image the insides of a body lumen. The essential components can be a part of or attached to a medical device that is inserted into the body lumen, such

as a needle, stent, endoscope or a swallowable capsule. The external magnet is part of or attached to the medical device package and is removed once the device package is removed.

The present invention further relates to a packaging suitable for storing therein an imaging system, said package comprising a magnet. The imaging system comprises components essential to an image collecting process, said components operable in accordance with the invention.

The present invention still further relates to a method for imaging a body lumen comprising the steps of:

a) providing an imaging system inserted in a balancing cup, said imaging system comprising a camera system having video output; an optical system for imaging an area of interest onto said camera system; a transmitter which transmits the video output of said camera system;

b) activating within the imaging system an image collecting process;

c) releasing the imaging system from the balance cup; and

d) inserting the imaging system into a body lumen.

The imaging system may also comprise other components such as a light source for illuminating an area of interest, a reception system which receives the transmitted video output, etc.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be understood and appreciated more fully from the following detailed description taken in conjunction with the appended drawings in which:

Fig. 1 is a schematic illustration of a prior art swallowable capsule comprising an imaging device;

Fig. 2 is a schematic illustration of an imaging device in a package in accordance with an embodiment of the invention; and

Fig. 3 is a side view of the imaging device and package illustrated in Fig. 2.

Fig. 4 is a block diagram of the method of the invention according to an embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

The method of the present invention comprises the step of releasing the power source of any component essential to an image collecting process, of an inhibition imposed by an external magnet.

The essential components are those power source driven components whose operation is necessary for obtaining images. Essential components for obtaining images are, for example, an imaging device or an illumination source (depending on the requirements and sensitivity of the imaging device). The imaging device can be any image sensor suitable for use in the method of the present invention, such as CCD cameras or CMOS image sensors. The energy for the imaging device is usually supplied through a low energy motor comprising either an electrical or permanent magnet.

The external magnet can be either more powerful than the essential component motor magnet or aligned with the essential component motor magnet such as to neutralize its magnetic field. Thus, proximity of the external magnet to the essential component power source or motor acts to inhibit the activation of the image collecting process since components essential for the image collecting process are not operative.

The external magnet may be distanced from the essential component power source or motor, so as to enable the essential component operation, directly by an operator or by mechanical or other means, suitable for distancing the external magnet from the essential component power source or motor.

In one embodiment of the invention an imaging device is attached to or is a part of a medical device that is suitable for imaging the inside of body lumens, such as blood vessels, the gastrointestinal tract, etc. The medical device may be a stent, needle, endoscope or swallowable capsule, or any other device suitable for being inserted into body lumens.

Reference is now made to Fig. 1 which shows a schematic illustration of a prior art swallowable capsule comprising an imaging device. Such a swallowable capsule is described in US 5,604,531. US 5,604,531, which is assigned to the common assignees of the present invention, is hereby incorporated by reference.

Swallowable capsule 10 typically comprises a viewing unit 11 and a unit 12 housing the electrical elements of the capsule. The viewing unit 11 contains an imaging system which includes a light source 18, a viewing window 14 through which the light illuminates the inner portions of the digestive system, the image collector component of an imaging device 16, such as a charge coupled device (CCD) camera, which detects the images, an optical system (not shown) which focuses the images onto the image collector component of the imaging device 16, and means for transmitting the video signal of the imaging device. The imaging system may also include a reception system which is in communication with the imaging device and which receives the transmitted video output.

The unit 12 typically includes the electronics and power source for producing a video signal from the output of the CCD device and a power source, such as a battery, which provides power to the entirety of electrical elements of the capsule.

Reference is now made to Figs. 2 and 3 which are schematic overview and side views of a swallowable capsule 20 in a package 22 in accordance with an embodiment of the invention. Capsule 20 is similar to the capsule described in Fig. 1. The viewing unit of the capsule 20 is inserted in a white balance cup 26, which in turn is attached to a holder 28, for sterile handling of the capsule 20. Capsule 20, holder 28 and balance cup 26 are encased in package 22 which comprises a magnet 24. The package 22 also includes a base 23 (Fig. 3) and a transparent sterile upper plastic cover 21 (Fig. 3). The magnet 24 is positioned in alignment with the encased capsule 20 such that the magnet 24 inhibits the imaging device power source or inhibits the battery which provides power to the entirety of electrical elements of the capsule.

The magnet 24 may be ring shaped or curved (as illustrated in Fig. 2) so that no specific directionality of the capsule, in relation to the magnet, is required.

The imaging system in capsule 20, while the capsule 20 is still in the package 22, is inactive due to the proximity of the magnet 24. The imaging device and/or other power source driven components of the capsule 20 are activated once the capsule is distanced from the magnet 24, namely by removing the capsule 20 from the package 22. The capsule 20 may be removed from the package 22 by peeling off either base 23 or cover 21 in the direction shown by arrow 25 and extracting the holder 28, balance cup 26 and capsule 20 inserted therein.

The package 22 may be made of any material suitable for storing capsule 20. For example, package 22 may be a blister type package in which cover 21 is made of a firm but flexible plastic and base 23 is a foil of material

which can be ruptured by pressure applied by a user. Capsule 20 is released from the package 22 by exerting pressure on it, through the cover 21 in the direction of the base 23 of the package 22, until the base 23 is ruptured, releasing the holder 28, balance cup 26 and capsule 20 inserted therein.

Once the capsule 20 is released from package 22 it is distanced from magnet 24 and the imaging device and/or other components essential for the imaging collecting process in capsule 20 are activated and the imaging system begins capturing images. Having the viewing unit of the capsule 20 inserted in a white balance cup 26, ensures that the first images captured and transmitted are white, thus enabling automatic white balance. The capsule 20 can be snapped out of the balance cup 26 to be swallowed by the patient.

In another embodiment the balance cup is marked on its inner wall, which is the wall being imaged once the image collecting process initiates. The image collecting process is operated for a predetermined initial period, prior to being released from the balance cup, during which identification of the mark is preformed. The image collecting process will be allowed to proceed only if identification of the mark is positive.

The mark may be a company logo or any other emblem or string of characters. The mark may be used, inter alia, to ensure that all parts of the imaging system are compatible, for example, that the capsule and its imaging device are compatible with the reception system and its software.

This point is demonstrated by the block diagram presented in Fig. 4.

Inhibition of the power source of any component essential to the image collecting process is removed (32) and the image collecting process initiates (34).

As discussed above, the first images collected will be images of the balance cup inner walls and of any mark on the balance cup inner wall. This initial data received from the imaging device is perceived by a reception system which is in communication with the imaging device and a process of identification of the mark (36) is initiated. The following factors, for example, might require adjustment for accurate identification of the mark:

a) The light conditions might vary between different capsules due to environment light and due to differences in the electronic components of the capsule (such as the light source and sensor);

b) The capsule and balance cup are not necessarily aligned, which will cause the image of the mark to appear in a different rotation angle each time;

c) The distance from the actual image is not accurate which results in different sizes of the object in the image; and

d) The image of the mark needs to be compared to a reference image and similarity needs to be confirmed.

Various algorithms may be executed to ensure accurate identification of the mark. For example, the following algorithms are executed in order to overcome the above:

Light correction (36a) is performed using an algorithm similar to AGC (Automatic Gain Control). This algorithm measures some statistical parameters of the input image. (The image is divided into 8x8 blocks and the average intensity is calculated. From this array average intensity and minimum and maximum block

intensity are calculated.) Next, the brightness and contrast of the image are changed in order to bring the statistical parameters to a reference value.

In order to correct rotation (36b) the image is converted from Cartesic coordination into polaric coordination (from X,Y plane into R ,Theta plane), where R = SQRT (X*X + Y*Y) and Theta = ATAN(X/Y).

After the conversion of the image into R, Theta plane, the magnification is corrected (36c) by applying a LOG function to the image. This function converts magnification, which is actually multiplication by a factor, into a bias/shift difference.

The identification of the mark is done by an image identification process (36d) in which the cross correlation function between a reference image and the input image is calculated and the maximum value of this cross correlation function is calculated. This maximum value is compared to a threshold. If it is higher than the threshold then the conclusion is that the images are similar.

If the result is that the images are similar (identification is positive), the image collecting process is allowed to proceed (35). If the result is that the images are not similar (identification is negative), the image collecting process is terminated (37).

Thus, the system will operate initially, for a predetermined time or to collect a predetermined number of frames, but the image collecting process will be allowed to continue further than the initial operation only if identification of the mark is positive. This mode of operation can be utilized to ensure that the system will only operate when all its components are the original components. For example, an original reception system that is used with a swallowable capsule

from a different make (that does not have a marked balance cup) will not operate after the initial operation, because there will not be a positive identification of the mark.

The patient may be alerted if the image collecting process has terminated before swallowing the capsule.

The fact that the system is inoperable when unauthorized components are being used and the fact that the patient is warned greatly contributes to the patient's safety.

It will be appreciated that algorithms and calculations are carried out by software or software means executable on computing means such as a computer or similar data processors, microprocessors, embedded processors, microcomputers, micrcontrollers etc.

The capsule may be utilized for diagnostic purposes or can be implemented in therapeutic processes. The capsule can also include any known system for collecting or releasing substances from or into the gastrointestinal tract environment, such that samples may be collected or medicaments may be released from the capsule at required points along the gastrointestinal tract. It will be appreciated that the image collecting process enables precise identification of required points and accurate localization of the capsule along the tract.

The method and packaging of the present invention enable safe activation of an image collecting process directly prior to use thereby providing safe, economic and facile use of components in an image collecting process.

It will be appreciated by persons skilled in the art that the present invention is not limited by what has been particularly shown and described herein above. Rather the scope of the invention is defined by the claims which follow:

CLAIMS

1. A method for activating an image collecting process, comprising the step of releasing the power source of at least one component essential to the image collecting process from an inhibition imposed by an external magnet.

2. A method according to claim 1 wherein releasing the power source of a component essential to the image collecting process from an inhibition is achieved by distancing the power source from the external magnet by a distance that is required to release the inhibition of the external magnet from the power source.

3. A method according to claim 1 wherein the essential component power source comprises a magnet.

4. A method according to claim 1 wherein the component essential to the image collecting process is an imaging device.

5. A method according to claim 4 wherein the imaging device is a CCD camera or a CMOS type image sensor.

6. A method according to claim 1 wherein the component essential to the image collecting process is an illumination source.

7. A method according to claim 1 wherein the image collecting process is designed to image the insides of body lumens.

8. A method according to claim 1 wherein the component essential to the image collecting process is a part of or attached to a device capable of being inserted into a body lumen.

9. A method according to claim 8 wherein the device is a swallowable capsule.

10. A packaging suitable for storing therein an imaging system, said package comprising an external magnet.

11. A packaging according to claim 10 wherein the imaging system comprises at least one component essential to an image collecting process.

12. A packaging according to claim 11 wherein the essential component is power source run, said power source comprising a magnet.

13. A packaging according to claim 11 wherein the external magnet is capable of inhibiting the essential component power source.

14. A packaging according to claim 12 wherein the external magnet is capable of inhibiting the essential component power source.

15. A packaging according to claim 11 wherein the essential component is a part of or connected to a device capable of being inserted into a body lumen.

16. A packaging according to claim 15 wherein the device is a swallowable capsule.

17. A swallowable capsule comprising an imaging system for imaging the gastrointestinal tract, said capsule being stored in a packaging comprising a magnet.

18. swallowable capsule according to claim 17 wherein an image collecting component of the imaging system is inserted in a balance cup prior to swallowing and is released from the balance cup at the time of swallowing.

19. A method for imaging the inside of a body lumen comprising the steps of

providing an imaging system inserted in a balancing cup, said imaging system comprising a camera system having video output, an optical system for imaging an area of interest onto said camera system and a transmitter which transmits the video output of said camera system;

activating within the imaging system an image collecting process;

releasing the imaging system from the balance cup; and

inserting the imaging system into the body lumen.

20. A method according to claim 19 wherein the imaging system further comprises a reception system which receives the transmitted video output.

21. A method according to claim 19 wherein the imaging system is a part of or connected to a device capable of being inserted into a body lumen.

22. A method for imaging the gastrointestinal tract comprising the steps of

providing a swallowable capsule comprising an imaging system which comprises a camera system having an image collecting component and having video output, an optical system for imaging an area of interest onto said camera system and a transmitter which transmits the video output of said camera system, said image collecting component being inserted in a balancing cup;

activating within the imaging system an image collecting process;

releasing the image collecting component from the balance cup; and

swallowing the capsule.

23. A method according to claim 22 wherein the imaging system further comprises a reception system which receives the transmitted video output.

24. A method according to claim 22 further providing an external magnet which inhibits the image collecting process and wherein activating the image collecting process is achieved by distancing the external magnet from power source driven components essential to the image collecting process by a distance that is required to release the inhibition of the external magnet from the components essential to the image collecting process power source.

25. A method according to claim 19 or 22 wherein the balancing cup has a mark on its inner wall.

26. A method according to claim 25 further comprising the step of identification of the mark prior to the step of releasing the image collecting component from the balance cup.

27. A method according to claim 26 wherein the step of identification of the mark comprises determining whether the identification is positive or negative and wherein the image collecting process is allowed to proceed only if the identification is positive.

28. A method according to claim 27 wherein a patient is alerted if the identification is negative, prior to releasing the image collecting component from the balance cup.

29. A system for imaging the gastrointestinal tract comprising a swallowable capsule and a balancing cup, said capsule comprising an imaging system and being inserted in the balancing cup prior to activation of the imaging system.

30. A system according to claim 29 wherein the balancing cup has a mark on its inner walls and wherein the imaging system initially images the mark and is allowed to proceed only after positive identification of the mark.

31. A system according to claim 30 wherein positive identification of the mark is done by establishing that the mark is similar to a reference mark.

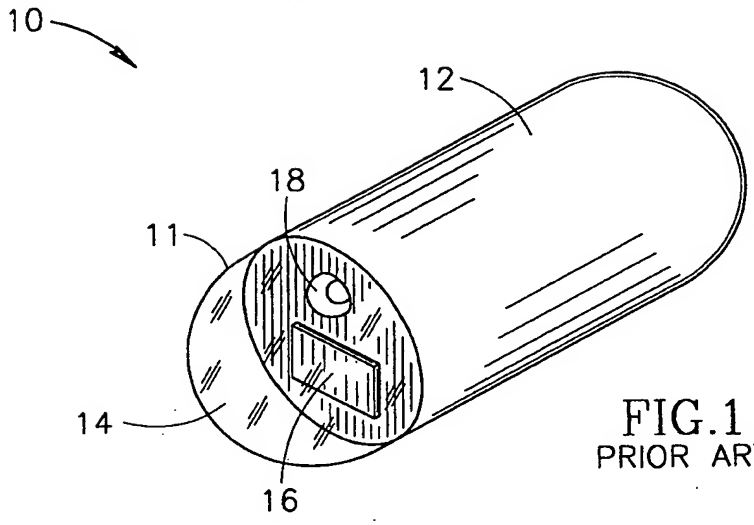

FIG.1
PRIOR ART

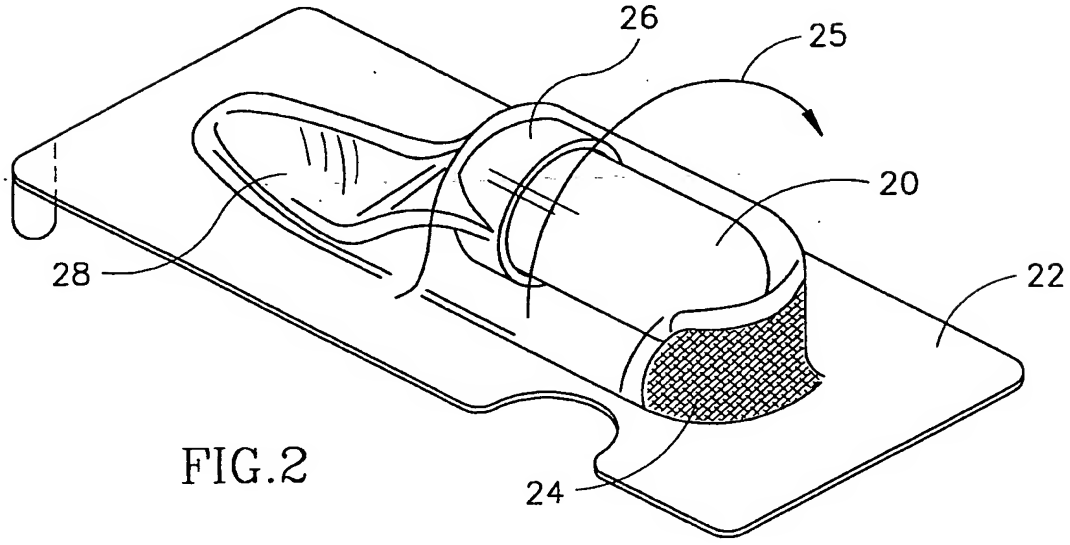

FIG.2

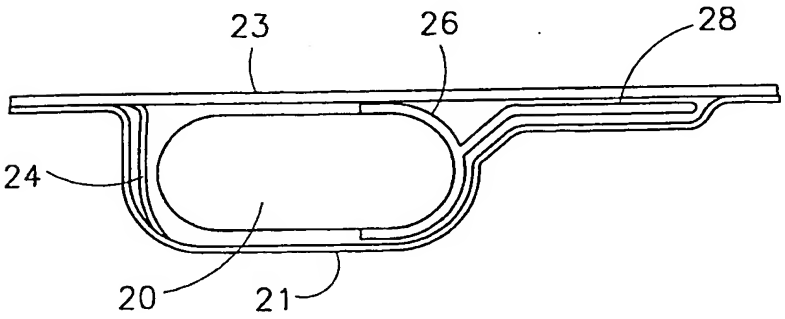

FIG.3

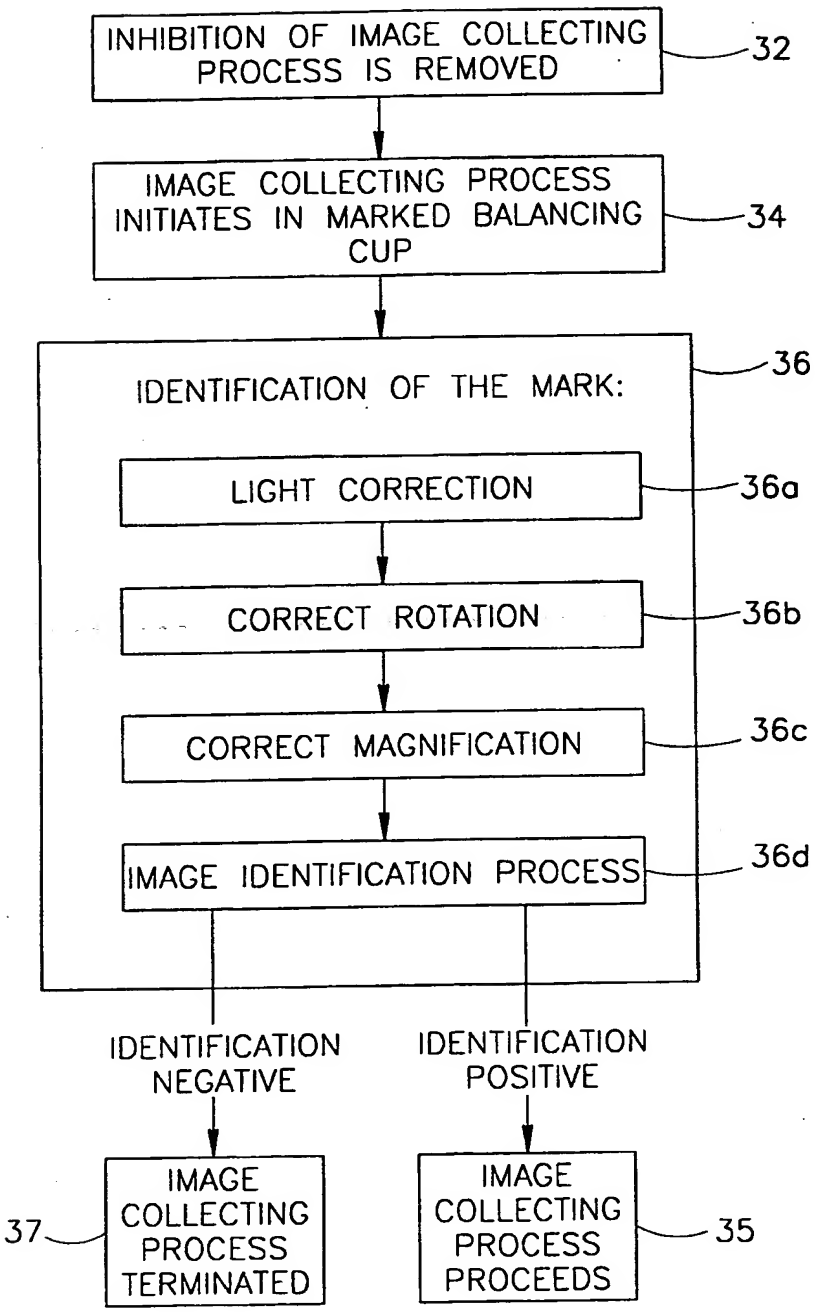
INHIBITION OF IMAGE COLLECTING PROCESS IS REMOVED
32
IMAGE COLLECTING PROCESS INITIATES IN MARKED BALANCING CUP
34
IDENTIFICATION OF THE MARK:
36
LIGHT CORRECTION
36a
CORRECT ROTATION
36b
CORRECT MAGNIFICATION
36c
IMAGE IDENTIFICATION PROCESS
36d
IDENTIFICATION NEGATIVE
IDENTIFICATION POSITIVE
IMAGE COLLECTING PROCESS TERMINATED
37
IMAGE COLLECTING PROCESS PROCEEDS
35

FIG.4

INTERNATIONAL SEARCH REPORT

International application No.
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A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :Please See Extra Sheet.
US CL :600/109,188,407,424; 396/17,180; 348/65,76,77,84,85; 340/321
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/109,188,407,424; 396/17,180; 348/65,76,77,84,85; 340/321

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,967,979 A (TAYLOR et al.) 19 October 1999, cols. 1-2	1-16, 19-24
A	US 5,604,531 A (IDDAN et al.) Febuary 1997, Fig. 2	17-24, 29-31
A	US 5,414,405 A (HOGG et al.) 09 May 1995, col. 4	1
A	US 5,257,636 A (WHITE) 02 November 1993, Fig. 6 & col. 6	1
X	US 4,278,077 A (MIZUMOTO) 14 July 1981, Fig. 1	10-12,
A		15-17 18, 29

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

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INTERNATIONAL SEARCH REPORT

International application No.
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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,172,640 A (LAND) 30 October 1979, col. 7	1,2,4,6,10
A	US 4,135,512 A (GODSEY) 23 January 1979, Figs. 1 & 3	19,22,29
A	US 4,273,431 A (FARMER et al.) 16 June 1981, col. 10	3-4, 11, 20, 21, 23

INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER:
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